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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,328	01/23/2001	Satoshi Sasaki	Q62621	4446

7590 02/11/2002

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 02/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/744,328

Applicant(s)

SASAKI ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

1. Group I, claims 1-5, 11-17, 23-29, 35 and 36, drawn to a pharmaceutical composition having an inhibitory effect on the overproduction and the accumulation of extracellular matrix, comprising a compound having an inhibitory effect on the biological activity of galectin-3, where the compound is anti-galectin 3 antibody, the use of a compound for the production of a pharmaceutical composition, and a method for inhibition of the overproduction and the accumulation of extracellular matrix, comprising administering the compound to a subject which needs inhibition.
2. Group II, claims 1-4, 6, 11-16, 18, 23-28, 30, 35 and 36, drawn to a pharmaceutical composition having an inhibitory effect on the overproduction and the accumulation of extracellular matrix, comprising a compound having an inhibitory effect on the biological activity of galectin-3, where the compound is an inhibitor of galectin-3 binding (e.g., sugar), the use of a compound for the production of a pharmaceutical composition, and a method for inhibition of the overproduction and the accumulation of extracellular matrix, comprising administering the compound to a subject which needs inhibition.

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3. Group III, claims 1-4, 7, 11-16, 19, 23-28, 31, 35 and 36, drawn to a pharmaceutical composition having an inhibitory effect on the overproduction and the accumulation of extracellular matrix, comprising a compound having an inhibitory effect on the biological activity of galectin-3, where the compound that inhibits the binding of galectin-3 to cell (e.g., antagonist of galectin-3 receptor), the use of a compound for the production of a pharmaceutical composition, and a method for inhibition of the overproduction and the accumulation of extracellular matrix, comprising administering the compound to a subject which needs inhibition.

4. Group IV, claims 1-4, 8, 11-16, 20, 23-28, 32, 35 and 36, drawn to a pharmaceutical composition having an inhibitory effect on the overproduction and the accumulation of extracellular matrix, comprising a compound having an inhibitory effect on the biological activity of galectin-3, where the compound that modulates the transfer of galectin-3 into the nucleus (e.g., inhibitors of galectin-3 transporter protein), the use of a compound for the production of a pharmaceutical composition, and a method for inhibition of the overproduction and the accumulation of extracellular matrix, comprising administering the compound to a subject which needs inhibition.

5. Group V, claims 1-4, 9, 11-16, 21, 23-28, 33, 35 and 36, drawn to a pharmaceutical composition having an inhibitory effect on the overproduction and the accumulation of extracellular matrix, comprising a compound having an inhibitory effect on the biological activity of galectin-3, where the compound that inhibits the physiological activity of galectin-3 in the nucleus or the cytoplasm (e.g., galectin-3 binding protein), the use of a compound for the production of a pharmaceutical composition, and a method for inhibition of the overproduction

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and the accumulation of extracellular matrix, comprising administering the compound to a subject which needs inhibition.

6. Group VI, claims 1-4, 10-16, 22-28 and 34-36, drawn to a pharmaceutical composition having an inhibitory effect on the overproduction and the accumulation of extracellular matrix, comprising a compound having an inhibitory effect on the biological activity of galectin-3, where the compound that modulates the expression or secretion of galectin-3 (e.g., antisense of galectin-3 gene), the use of a compound for the production of a pharmaceutical composition, and a method for inhibition of the overproduction and the accumulation of extracellular matrix, comprising administering the compound to a subject which needs inhibition.

The claims of these groups are directed to different inventions, which are not linked to form a single general concept. The claims in the different groups do not have in common the same or corresponding technical features. In particular, each group is directed to distinct chemical entities and/or methods, which use different materials and produce different effects. Accordingly, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept and lack of unity is deemed proper.

If any one of Inventions I-VI is elected, the examination of the elected invention will be carried out only in-so-far as it pertains to the subject matter of the elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

February 8, 2002

Karen Cochrane Carlson PhD
KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER